DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

JUL 27 2015

Boston Scientific Corporation, Endoscopy
Mr. James D. McMahon
Senior Regulatory Affairs Specialist
One Boston Scientific Place
Natick, MA 01760-1537

Re: K040148
Trade/Device Name: Resolution™ Hemostasis Clipping Device
Regulation Number: 21 CFR 876.4400
Regulation Name: Hemorrhoidal ligator
Regulatory Class: II
Product Code: FHN, MND, MCH
Dated (Date on orig SE ltr): January 22, 2004
Received (Date on orig SE ltr): January 23, 2004

Dear Mr. McMahon,

This letter corrects our substantially equivalent letter of April 22, 2004.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number	~~To be determined~~ K040148
Device Name	Resolution™ Hemostasis Clipping Device
Indications For Use	Indicated for endoscopic clip placement within the gastrointestinal tract for the purpose of : - endoscopic marking - hemostasis for mucosal/submucosal defects <3cm, bleeding ulcers, arteries <2mm, polyps <1.5cm in diameter, diverticula in the colon - anchoring to affix jejunal feeding tubes to the wall of the small bowel - as a supplemental closure method of luminal perforations <20mm that can be treated conservatively.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over the Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040148

K040148

APR 2 2 2004

510 (k) SUMMARY

SPONSOR:	Boston Scientific Corporation One Boston Scientific Place Natick, MA 01760
CONTACT PERSON:	James D. McMahon Senior Regulatory Affairs Specialist
DEVICE:	
Trade Name:	Resolution™ Hemostasis Clipping Device
Common Name:	Endoscopic Clipping Device
Classification:	Class II, per 21 CFR Part 876.4400
PREDICATE DEVICE:	Olympus Clip Fixing Device (K013066, K990687, K963160)
DESCRIPTION:	The Resolution™ Hemostasis Clipping Device is a single-use pre-loaded mechanical clip and delivery system used for endoscopic clipping.
INTENDED USE:	The Resolution™ Hemostasis Clipping Device is intended for the treatment of peptic ulcer bleeding, post polypectomy bleeds, wound closures, and general endoscopic closure that can be deployed through a standard flexible gastroscope and colonoscope.
COMPARISON OF CHARACTERISTICS:	The Resolution™ Hemostasis Clipping Device is substantially equivalent to the predicate Olympus Clip Fixing devices, as they have similar technological characteristics. The results of performance testing shows no new issues of safety or effectiveness.
PERFORMANCE DATA:	FDA's "Guidance for the Content of Premarket Notifications", and the results of technological characteristics and functional testing support a determination of substantial equivalence for the new device when compared to the predicate device. The Resolution™ Hemostasis Clipping Device is substantially equivalent to the currently marketed Olympus Rotatable Clip Fixing Device (K013066).